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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,778	11/28/2000	Jeffrey T. Finer	CYTOP009C1	9331

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/08/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/724,778

Applicant(s)

FINER ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 7-19, 30, and 60-82 is/are pending in the application.
- 4a) Of the above claim(s) 60-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7-19, 30, and 63-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.                      6) ☐ Other:

### **FINAL ACTION**

Applicant's amendment and IDS of 5-27-03 have been considered. The amended claim 12 has overcome the previous rejection of 112/2<sup>nd</sup> paragraph. However, applicant's argument has not overcome the previous 103 rejection because the argument fails to address the commercially available compounds disclosed by ComGenex, and Maybridge Catalog (which are cited by applicants). Thus, the 103 rejection is maintained herein.

The newly submitted IDS cites a new reference which prompts the following new ground of rejection. New claims also necessitate new ground of rejection under 35 USC 112/2<sup>nd</sup> paragraph.

Pending claims are 1, 4, 7-19, 30, and 63-82.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 74, and 77-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 74 appears as a substantial duplicate of claim 18 because it practically recites the same method as claim 18 although the dependency is different.

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- b. Although the dependency is different, claims 77-79 are substantial duplicates of each other because they recites the same method of treatment using the same compounds. They are also substantial duplicates of claim 65.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **New Matter:** Claims 80-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The particular salts of “mesylate” do not have support in the instant disclosure.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1),

(2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 4, 7-17, 30, 64, 68-72, and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by **Baxter et. al.** (US 6,545,005 B1). Said reference discloses many compounds (e.g, see Fig. 32a, compounds #33, 34; Fig. 32b, compound #38; Fig. 32c, compounds #39-41). Said compounds are embraced by the claimed formula with the following substituents:

- i.  $R_1$  is a substituted aryl;
- ii. One of  $R_2$  and  $R_2'$  is hydrogen while the other is alkyl;
- iii.  $R_3$  is alkyl or substituted aryl;
- iv.  $R_4$  is alkyl or alkylaryl.

**Baxter et. al.** also apply their compounds in the treatment of various cancers and tumors (see column 45, lines 4-18), which are also known as cellular proliferative diseases. Thus, the teaching of **Baxter et. al.** reads on all the limitations of the above claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4, 7-19, 30, and 63-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over commercially available compounds from ComGenex, and Maybridge Catalog in view of Aono et. al. (US'664). The rejection is maintained for the reason stated above and for the one herein.

Applicant asserted that Aono et. al. did not disclose compounds of quinazolinone substituted with *an amide* at the second position, and thus, cannot renders obvious the instant method claims. However, the teaching of Aono et. al. was not relied on for rendering obvious the claimed compounds. Some of these claimed compounds are **commercially available**. The teaching of Aono et. al. was relied on for the recognition that substituted quinazolinone compounds (**as a class**) can treat tumors, or cellular proliferative diseases. Note, on column 2 of US'664, the generic formula I has Z as simply a "divalent group". Thus, the disclosed formula I describes a 'class of compounds' that have antitumor activity.

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Therefore, with ComGenex and Maybridge provide quinazolinone compounds substituted with amide, one of the ordinary skill in the art can look to the teaching of Aono et. al., and apply them in the treatment of cellular proliferative diseases.

Thus, at the time of the invention, it would have been obvious to use quinazolinone compounds as claimed herein in the treatment of cellular proliferative diseases.

5. Claims 1, 4, 7-19, 30, and 63-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over commercially available compounds from ComGenex, and Maybridge Catalog in view of **Baxter et. al.** (US'005). Again, said catalogs provide quinazolinone compounds that are embraced by the claimed formula with R<sub>4</sub> as “dimethylamino-propyl”, “dimethylamino-ethyl”, and “alkylheteroaryl”. Baxter et. al. teaches a class of substituted amide-quinazolinone compounds (see formula II on column 9) which can treat cellular proliferative diseases. Thus, at the time of the invention, it would have been obvious to one skilled in the art to use the claimed compounds in view of the commercially available compounds and the teaching of Baxter et. al.

Applicant's amendment and IDS necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
T. Truong

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August 1, 2003

  
MUKUND J. SHAH  
SUPERVISORY PATENT EXAMINER  
GROUP 1600